

SEP 12 2002

K022872

## Attachment B:

*Summary of Safety and Effectiveness  
Prepared in accordance with 21 CFR Part 807.92(c).*



GE Medical Systems

General Electric Company  
P.O. Box 414, Milwaukee, WI 53201

Submitter: GE Medical Systems  
PO Box 414  
Milwaukee, WI 53201

Contact Person: D. Duersteler  
Safety and Regulatory Engineering  
Telephone: 262-312-7029; Fax: 262-312-7144

Date Prepared: August 23, 2002

Device Name: GE Road Warrior PET CT Imaging System.  
Emission Computed Tomography System, 21 CFR 892.1200, 90-KPS

Marketed Device: GE Medical Systems GE Discovery LS Positron Emission Tomography System, 510(k)  
Number K010641, currently in commercial distribution.

Device Description: The GE Road Warrior PET CT Imaging System integrates a GE Positron Emission Tomography system and a GE LightSpeed Ultra CT System. In addition to providing CT and PET stand-alone capabilities, it uses the CT images to correct for non-uniform attenuation of the PET images and to facilitate localization of the emission activity in the patient anatomy.

Indications for Use: The GE Road Warrior PET CT Imaging System is intended for use in head and whole body attenuation corrected Positron Emission Tomography (PET) imaging, facilitating localization of emission activity in the patient anatomy by means of integrated CT and PET images, and stand alone head and whole body multislice X-ray computed tomography diagnostic imaging.

Comparison with Predicate Device: The GE Road Warrior PET CT Imaging System is of a comparable type and substantially equivalent to the currently marketed GE Discovery LS CT-PET System. It has the same technological characteristics, is comparable in key safety and effectiveness features, uses the same basic design, construction, and materials, and has the same intended uses as the predicate device.

Summary of Studies: The device has been evaluated for electrical, mechanical, and radiation safety, and conforms with applicable medical device safety standards.

Clinical Tests: None required.

Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. Intended uses and fundamental scientific technology are the same as the legally marketed GE Discovery LS CT-PET System. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001 and EN 46001 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with factory surveillance. Therefore, it is the opinion of GE Medical Systems that the GE Road Warrior PET CT Imaging System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 12 2002

Mr. David Duersteler  
Safety and Regulatory Engineering  
GE Medical Systems  
P.O. Box 414  
MILWAUKEE WI 53201

Re: K022872  
Trade/Device Name: GE Road Warrior PET  
CT Imaging System  
Regulation Number: 21 CFR 892.1200  
Regulation Name: Emission computed  
tomography system  
Regulatory Class: II  
Product Code: 90 KPS  
Dated: August 23, 2002  
Received: August 29, 2002

Dear Mr. Duersteler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

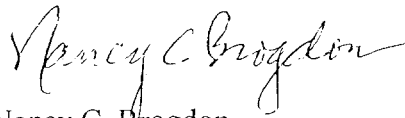
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

Special 510(k) Premarket Notification  
GE Medical Systems - GE Road Warrior PET CT System  
August 23, 2002

STATEMENT OF INTENDED USE

510(k) Number (if known): K022872

Device Name: GE Road Warrior PET CT Imaging System

Indications for Use

The GE Road Warrior PET CT Imaging System is intended for use in head and whole body attenuation corrected Positron Emission Tomography (PET) imaging, facilitating localization of emission activity in the patient anatomy by means of integrated CT and PET images, and stand alone head and whole body multislice X-ray computed tomography diagnostic imaging.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801-109)

OR Over-The-Counter Use \_\_\_\_\_

David A. Segerson  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K022872